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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,819	01/30/2001	Kathleen E. Rodgers	98,365-B1	3008

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EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,819

Applicant(s)

RODGERS ET AL.

Examiner

Maury Audet

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49, 54, 62, 65 and 67-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49, 54, 62, 65 and 67-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

The response of 2/10/2004 is acknowledged. The Terminal Disclaimers disclaiming any terms beyond either U.S. Patent No.:s 6,248,587 and 6,498,138, are also acknowledged. It is noted that other peptides other than elected SEQ ID NO: 18 remain in the claims. The claims have only been searched and examined on the merits as drawn to SEQ ID NO: 18.

Claim Rejections - 35 USC § 112 1st Written Description

The rejection of claims 49, 54, 62, 65, and new claims 67-75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained for the reasons of record. Applicant's arguments have been fully considered but are not found persuasive. As indicated in the first action, "although the specification at page 36-37 describe that SEQ ID NOS: 1, 4, and 45 [although not elected SEQ ID NO: 18], may be useful (only 50% [of rats] were observed with new bone growth, the study was only conducted on rats, and the study does not indicate how many subjects were tested), as a therapeutic agent for "bone healing" and the formation of new bone; *SEQ ID NO: 18 has not been tested.*" Applicant has provided a 35 U.S.C. § 132 Declaration that certain peptides have been tested and (at least some) shown to have increased bone growth. However, it is still not described where SEQ ID NO: 18 worked to increase bone growth in those with weakened bones. Based on the low rate of new bone growth in only a few tested peptides, it cannot be stated that SEQ ID NO: 18 is 'ready for patenting', or that

Applicant has somehow described distinguishing characteristics sufficient to show that the applicant was in possession of the claim invention (namely, increasing bone growth with SEQ ID NO: 18).

Claim Rejections - 35 USC § 112 1st Enablement

The rejection of claims 49, 54, 62, 65, and new claims 67-75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for the reasons of record. Applicant's arguments have been fully considered but are not found persuasive. As indicated in the first action, "the specification does not teach the testing or capability of SEQ ID NO: 18, as a method for treating (or preventing) a bone disorder or a bone disorder that results in weakened bones." Applicant argues that "a large number of peptides falling under the claimed genus can be used to carry [out] the methods of the invention. Therefore, it is clear that the specification enables those of skill in the art to make and use the invention as claimed". In response to this argument, it is noted that the elected invention is a method of using SEQ ID NO: 18, not of using other peptides outside this particular sequence. Additionally, only 50% of those peptides tested showed increased bone growth, of which SEQ ID NO: 18 was not one of those tested.

In view of the lack of any demonstratable showing with respect to SEQ ID NO: 18 (as discussed above), those skilled in the art are unlikely to accept the data as being correlatable to providing sufficient evidence that SEQ ID NO: 18 can act as a therapeutic agent to effectively treat a bone disorder *in vivo* (i.e., increase bone growth *in vivo*), as instantly claimed.

Therefore, other skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success.

Claim Rejections - 35 USC § 112 1st Scope

The rejection of claims 49, 54, 62, 65, and new claims 67-75 under 35 U.S.C. 112, first paragraph, because the specification, while it may be enabling for treating and/or reducing the risk of a bone disorder or a bone disorder that results in weakened bones using SEQ ID NO: 1, 4, and 45 (non-elected sequences), does not reasonably provide enablement using the elected sequence - SEQ ID NO: 18 for the same purpose. As indicated in the first action, "Applicants have reasonably demonstrated/disclosed that SEQ ID NOS: 1, 4, and 45 (although not elected SEQ ID NO: 18), may be useful (only 50% were observed with new bone growth, the study was only conducted on rats, and the study does not indicate how many subjects were tested), as a therapeutic agent for "bone healing" and the formation of new bone and/or reducing the risk of bone disorders (specification page. 36-37).

Thus, again, in view of the lack of any demonstratable showing with respect to SEQ ID NO: 18 (as discussed above), those skilled in the art are unlikely to accept the data as being correlatable to providing sufficient evidence that SEQ ID NO: 18 can act as a therapeutic agent to effectively treat a bone disorder *in vivo* (i.e., increase bone growth *in vivo*), as instantly claimed.

Therefore, other skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success.

Claim Rejections - 35 USC § 112 2nd

The rejection of claims 49, 54, 62, 65, and new claims 67-75 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are each addressed individually below.

In claims 49, 54, 62, 65, and new claims 67-75, the invention is unclear since, as claimed, it is drawn to the use of a sequence outside of the elected sequence (SEQ ID NO: 18) – i.e. a sequence of at least [seven] contiguous amino acids, many alternatives, including sequences, thereof. It is also noted that “comprising” language has been maintained (see claim 49 and 54), although the elected invention is only drawn to SEQ ID NO: 18. As indicated above, the claims have only been searched and examined as drawn to elected SEQ ID NO: 18. As previously discussed, it is strongly suggested that Applicant amend the claims to be drawn to elected specifically to elected SEQ ID NO: 18; however this was not done as evident in the amended claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
5/2/04



CHRISTOPHER R. TATE
PRIMARY EXAMINER